

REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 52-55, 79-85, 87, and 101-123 are in this Application. All claims have been rejected under 35 U.S.C. § 112. Claims 52-55, 79-85, 87 and 101-112 have been rejected under 35 U.S.C. § 102. Claims 53, 54, 83 and 84 have been rejected under 35 U.S.C. § 103. Claims 52, 53, 79, 82, 101 and 107 have been amended herewith. New claims 113-123 have been added herewith.

The amendments in the application are based, in part on the arguments and amendments made in a related case, U.S. Patent Application No. 10/570,576, recently interviewed by and responded to by the applicants.

Priority

As in the related case, the Examiner has argued there is no support for the claim in the priority applications. However, as argued in the related case, attachment of an electrode to muscle, for controlling of blood glucose level is specifically taught even in the priority document. This is found, for example, in the section “TYPES OF ELECTRODES” in the description of Fig. 4E. The additional amendments regarding pulse sequence are supported, for example, on page 20 thereof.

35 U.S.C. § 112 Rejections

Claims 53 and 54 are rejected as failing to comply with the written description requirement. The Examiner did not find support for the limitations “more than necessary...” (claim 53) and “sufficient to reduce...” (claim 54).

With respect to claim 53, applicants respectfully disagree. Original claim 53 states that the stimulation is applied using a closed loop and the circuitry is configured to “overstimulate” in case of “doubt”. While there has been a rejection in the past (December 8, 2008) that “doubt” is not a technical term, the meaning is clear. Similarly, the Examiner was argued that “over-stimulate” is also not a clear term. The circuitry stimulates more if the sensing cannot does not clearly indicate that no more stimulation is needed. This is how the claim was reworded - with the same scope, but using more technical language. Claim 53 is also slightly amended, herewith. The Examiner is requested to suggest alternative language if he feels that the claim is still not supported. Alternatively, the Examiner is requested to explain how the scope of

current claim 53 is different from that of original claim 53. In addition, an example of such over stimulation is described, for example, at page 43 (“open loop logic”).

With respect to claim 54, applicant also disagrees. For example, the same section (“open loop logic”), the first paragraph on page 5 and original claim 54, describe reducing glucose levels to normal levels without feedback. A specific example is shown in the Experiments (e.g., pages 71-72 and 72-73), in which no feedback was used in deciding the stimulation protocol. Again, the Examiner is requested to indicate what part of the claim is not described, so that applicants may argue or excise the problematic section.

If the Examiner believes an interview will be helpful in settling this issue, an interview is hereby requested.

Claims 52-55, 79-85 and 101-112 are rejected under 35 U.S.C. 112 because the specification does not reasonably provide enablement for any and all parameters suitable for blood level glucose control. In response, Applicants have amended claim 52 to be more specific with respect to pulse parameters, and hope that the Examiner will agree that with the reduced claim scope, the requested claim scope is reasonably well supported. Applicants also direct the Examiner to the tables on Col. 11 of Wernicke cited by the Examiner, which suggest what was considered reasonable ranges, at least in 1991; similarly Marchal, col. 5 has similar specificity of teaching. Some new dependent claims are added as well, further limiting the manner in which the pulse is suitable for glucose control.

Claim 53 is rejected because the terms “desires” and “sufficient or insufficient” are said to be unclear. Claim 53 has been amended and it is hoped that these rejections are no overcome.

Claim 82 is rejected because no programmable element is supposedly described. While applicants believe the claim was clear before, it has now been amended and the rejection should be withdrawn. Support is found all through the application, for example, in Fig. 7.

Claim 101 is rejected as the term “said field” is said to lack antecedent. Claim 101 has been amended to refer to “electrification” instead. It is believed the rejection is overcome.

Applicants wish to put the cited art, Wernicke and Marchal, in context. Wernicke is directed at a method of modulating pancreatic function by nerve stimulation. Such modulation is not shown to be effective for treatment of hyperglycemia and even for such treatment it is admitted that a closed loop using an unavailable sensor, is to be used.

Marchal, while using very general terms of what might be controllable in a pancreas and how this might be achieved, does not actually describe control of anything close to blood glucose levels, nor even suggest that such would be an aim of treatment using his system.

In contrast, the instant application, not only described various methods of controlling blood glucose levels; actual results showing that such control can be achieved using the methods described in the application are shown. Moreover, such control was shown to be potentially safe and avoid dangers known in the prior art and even, in some embodiments, provide control without using the “unavailable” glucose sensor.

35 U.S.C. § 102 Rejections

Claims 52-55, 79-85, 87 and 101-112 are rejected under 35 USC 102 as being anticipated by Wernicke. Applicants respectfully disagree.

The Examiner asserts that Wernicke is implicitly describing attaching the electrode to muscle tissue. However, in Wernicke it is the lead which is attached to “other tissue”, while the electrode is mounted on the nerve (see Fig. 3 and Col. 10, lines 22-46 and lines 47-65) and is specifically designed for this. As Wernicke is attempting to affect nerve tissue, it makes no sense that the electrode be mounted on muscle as this will not only make it more difficult to affect nerves, but also risk affecting the muscle tissue.

With regard to claim 53, over stimulating risks hypoglycemia and the Examiner has not shown any suggestion in the art that any such over stimulation is used, especially not in a safe manner. In particular, the Examiner has not shown that as part of a closed loop system over stimulation is employed.

With regard to claim 54, the art does not teach that the stimulation applied is sufficient to reduce glucose levels to normal.

With regard to claim 79, it is specifically taught in the art, for example at col. 9, line 41, that glucose level is reduced by insulin secretion. However, this claim has now been amended to prevent any misreading.

With regard to claim 107, Applicants believe the Examiner is misreading the claim. The claim does not merely state there is synchronization with electrical activity, but rather synchronization with the propagation of action potentials. The art does not relate to electrical activity at such a degree of detail and does not relate to action potentials or their propagation, merely, at most, to the overall existence of activity. The claim has been amended to relate to local activity which is clearly not shown in the art. The scope of the claim is unchanged.

With regard to claim 108, Applicants believe the Examiner has misconstrued the claim. In claim 108, it is the same field which reduces high levels but does not reduce low levels. In the cited art, this is a property of the logic of the circuitry, not of the field.

Claims 52, 55, 79-82, 85, 87 and 101-112 are rejected under 35 USC 102 as being anticipated by Marchal. Applicants respectfully disagree.

With respect to claim 52, it is argued that Marchal at cl. 3, lines 12-20 merely list secretions that may be affected. There is no teaching that the secretions may be affected in a manner compatible with glucose level control. In fact, none of the examples shown relate to affecting control of blood glucose levels, in spite of such control being, probably, significantly more important than the other example shown. As noted above, while glucose control is a medical problem affecting many more people than nausea in pregnancy (for example), there is no suggestion in Marchal to treat this important and well known clinical problem, which suggests that Marchal did not consider it possible or did not otherwise conceive of the possibility.

With regard to claim 55, open loop may be shown, but not for treatment of glucose disorders.

With regard to claim 107, as noted with respect to Wernicke, the cited section does not teach synchronization to specific electrical activity, but at most to the general fact of electrical activity.

Claims 53, 54, 83 and 84 are rejected under 35 USC 103 as being unpatentable over Marchal in view of Wernicke. Applicants respectfully disagree with the reasonableness of the combination.

Marchal is directed at pancreatic and other stimulation without the aim of glucose level control. Wernicke is specifically directed at glucose level control. A person of typical skill in the art would not consider protocols suitable for treating one family of conditions for use in another family of conditions., especially as the result of keeping blood glucose level accurately within acceptable limits is not actually taught in either patent and is definitely not predicable from the combination. Such a result is a holy grail of Diabetes management. See for example, Col. 2 of Wernicke, where the need is explained, however, while various protocols are suggested, no results are shown and there is no justification for any expectation that a treatment other than closed loop with stimulation (Col. 4, line 44-Col. 3, line 26) only to the amount indicated by the sensed glucose level would be used to provide actual control of hyperglycemia (cf. Col. 4, lines 16-30).

New claims

New claims 113-123 provide additional limitations in accordance with exemplary embodiments of the claimed invention.

For example, claims 113-14 relate to electrode design. Claims 115-118 and 123 relate to various pulse parameters. Claim 119 relates to not affecting nervous tissue (in distinct contrast to Wernicke and some embodiments of Marchal). Claims 120-121 relate to pacing (or not) of the stomach. Claim 122 relates to using feedback (not triggering) from a digestion sensor (e.g., not a glucose level sensor).

Double patenting

When claims are allowed and if still necessary, applicant intends to consider the filing of a terminal disclaimer.

In view of the above amendments and remarks it is respectfully submitted that claims 52-55, 79-85, 87 and 101-108 are now in condition for allowance. A prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,

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Enclosures:

- Petition for Extension (Three Months)
- Request for Continued Examination (RCE)